K092078

510(k) Summary

AUG 0 5 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter/Manufacturer:	Biomet Trauma 100 Interpace Parkway Parsippany, NJ 07054
Establishment Registration Number:	2242816
Contact:	Shikha Gola Regulatory Affairs Specialist Biomet Trauma 100 Interpace Parkway Parsippany, NJ 070654 Tel.: 973-299-9300 Fax: 973-257-0232 E-mail: shikha.gola@ebimed.com
Date Prepared:	June 29, 2009
Trade/Proprietary Name:	EBI OptiLock Periarticular Plating System
Common/Usual Name:	Internal Fixation Device
Classification Name:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, Smooth or threaded metallic bone fixation fastener, 21CFR 888.3030, 21 CFR 888.3040
Device Classification:	HRS, Plate, Fixation, Bone HWC, Screw, Fixation, Bone Class II
Legally Marketed Device Information:	Cleared through K061098 on May 24, 2006 and K042237 on September 16, 2004.
Device Description	This submission is being made for sterile packaging of plates and screws that comprise the OptiLock Periarticular Plating System.
Summary of Technologies:	The technological characteristics of the OptiLock Periarticular Plating System are the same as, or similar to the predicate devices.

K092078

Indications for Use:

The EBI OptiLock Periarticular Plating System (The System) is indicated for fixation of fractures and osteotomies involving the femur or tibia.

The System is intended for buttressing multifragment distal femur fractures including: supracondylar, intra-articular and extra-articular condylar fractures, fractures in normal or osteopenic bone and nonunions and malunions.

The System is intended for the treatment of non-unions, malunions and fractures of the proximal tibia, including simple, comminuted lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression and fractures with associated shaft fractures.

The System is intended to buttress Metaphyseal fractures of the medial tibial plateau, split-type fractures of the medial tibial plateau, medial split fractures with associated depressions and split of depression fractures of the medial tibia plateau. Also, for use in the fixation of osteopenic bone and fixation of nonunions and malunions for the medial proximal tibia and tibial shaft.

The System is indicated for the fixation of fractures of the distal tibia including, but not limited to, ankle fractures, periarticular, intraarticular and distal tibia fractures with a shaft extension, malleolar and distal fibular fractures.

Substantial Equivalence:

The OptiLock Periarticular Plating System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics and principles of operation and do not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

AUG 0 5 2009

Biomet Trauma
% Ms. Shikha Gola
Regulatory Affairs Specialist
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K092078
Trade/Device Name: EBI OptiLock Periarticular Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: July 8, 2009
Received: July 9, 2009

Dear Ms. Gola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter D Rumm MD PhD Dir D.R

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092078

Device Name: EBI OptiLock Periarticular Plating System

Indications for Use:

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Prescription Use X		Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) for MKM
Division of Surgical, Orthopedic,
and Restorative Devices